Claims

1. A pharmaceutical composition comprising an active pharmaceutical ingredient which exists in a first polymorph form susceptible to degradation or interconversion into one or more other polymorph forms, and further comprising a stabilizing substance selected from the group consisting of colloidal silicon dioxide, finely divided silicon dioxide, silicified microcrystalline cellulose, magnesium oxide, polyethylene glycol and croscarmellose sodium, and optionally one or more pharmaceutically acceptable excipients.

2. A pharmaceutical composition according to claim 1, wherein said active pharmaceutical ingredient is the potassium salt of losartan.

3. A pharmaceutical composition according to claim 2 wherein the potassium salt of losartan is in the amorphous form.

4. A pharmaceutical composition according to claim 2 wherein the potassium salt of losartan is in the polymorph form exhibiting its strongest diffractions in a powder X-ray diffractogram at around 2Θ = 6.9, 13.8, 20.6, 24.0, 24.8, 28.7 and 29,2°.

5. A pharmaceutical composition according to any preceding claim which is in the form of a coated tablet.

6. A pharmaceutical composition according to any preceding claim characterized in that it is coated with a film coating comprising stearic acid or ethylcellulose in an amount of from about 0.1% to about 1.7% by weight of the pharmaceutical composition.

7. A pharmaceutical composition according to any preceding claim wherein said stabilizing substance is finely divided anhydrous silicon dioxide or polyethylene glycol present in amount of about 1 % to about 10% by weight of the composition.

8. A pharmaceutical composition according to any preceding claim which is a finished dosage form comprising from about 1% to about 10% by weight of the composition of finely divided silicon dioxide.

9. A pharmaceutical composition according to claim 8 wherein said finely divided silicon dioxide is Syloid™.

10. A pharmaceutical composition according to claim 9 comprising from about 3% to about 10% by weight of the composition of Syloid™.

11. Use of a composition according to any preceding claim for the manufacturing of a medicament.

12. Use of a composition according to any preceding claim for the manufacturing of a medicament for treating hypertension and/or chronic renal failure.

13. Use of a composition according to any of the claims 1 to 11, where the composition comprises potassium salt of losartan for the manufacture of a medicament for treating hypertension and/or chronic renal failure,

14. A method of stabilization of an active pharmaceutical ingredient which can exist in more than one polymorph form, and which is susceptible to environmental influences comprising adding colloidal silicon dioxide, finely

divided silicon dioxide, silicified microcrystalline cellulose, magnesium oxide or polyethylene glycol to said active pharmaceutical ingredient.

15. A method of stabilization of an active pharmaceutical ingredient according to preceeding claim where the environmental influences cause conversion to another polymorph form.

16. A method of stabilization of an active pharmaceutical ingredient according to any of the claims 14 to 15 where the active pharmaceutical ingredient is losartan potassium.

17. Use of finely divided silicon dioxide for the stabilization of an active pharmaceutical ingredient which exists in a first polymorph form to prevent the conversion of the active pharmaceutical ingredient to other polymorph forms.